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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,146	11/17/2000	Christopher T. Boyle	6006-018	6734

7590

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 10/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/716,146

Applicant(s)

BOYLE, CHRISTOPHER T.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 April 2003 and 12 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16,20 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16,20 and 26-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 12, 2003 has been entered.

### ***Response to Arguments***

Applicant's arguments with respect to claims 2-10 and 12-25 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed August 12, 2003 in respect to the rejection over Brown et al. (USPN 6,071,305) have been fully considered but they are not persuasive. The applicant has argued that Brown does not disclose structural elements having separate layers, a layer being a single thickness or level of material. The examiner disagrees. Cross-sectional views of Brown's structural elements are shown in figures 3-10. Brown discloses the cross-section of structural elements to be shapes other than circular, such as square (col.5 line 65-col.6 line 5). If the cross-section of the structural elements is square, having a void space 20 therebetween, two layers are formed, a top layer and bottom layer, and the sides walls of the square cross-section enclose the void space (20) between the top and bottom layers. Brown has also shown in figure 12, a cross-section of a structural element, having a base layer, second layer covering the base layer, and a void layer therebetween

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16, 20, and 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al. (USPN 6,071,305, cited in previous office action). Referring to claim 16, Brown discloses an endoluminal stent (11) comprising a plurality of structural elements forming a radially expandable cylindrical member (although Brown has shown a helical stent made of one structural element, wires/fibers/filaments in this case, Brown also discloses use of stent with multiple structural elements, wires/fibers/filaments, col.7, lines 34-40), the structural elements (12) having a wall thickness (width of wire/fiber/filaments, shown in fig.5-9, Brown discloses the cross-sectional shape of the wire/fiber/filaments to be square, col.5 line 65-col.6 line 5, therefore the thickness is the width of the square cross section), wherein the structural elements (12) are comprised of a first region comprising a base layer (as seen in cross section, for example fig. 6 or 8, and imagining Brown's disclosed square cross-section, one side of the square is the base layer) and a second region comprising a second layer (as seen in cross section, for example fig. 6 or 8, and imagining Brown's disclosed square cross-section, the opposing side is the second layer) covering the base layer, the second region further comprising a layer of void space (cavity, 20) intermediate the base and second layers and enclosed therebetween (as seen in cross section, for example fig. 6 or 8, and imaging Brown's disclosed square cross-section, the void

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space 20 is enclosed by the side walls of the square) and a plurality of pores (pores may be openings 22, 28, 54; col.6, lines 12-21 or alternatively pores may be pores in the porous stent material col.10, lines 36-38) passing through at least one of the base and second layers and communicating with the void space (20) and at least one bioactive agent (23) retained within the void space (20) and elutable through the plurality of pores (22, 28, 54). Figure 12 shows another embodiment wherein the structural member has a base layer, a second layer covering the base layer and a void layer (channel) therebetween (col.11, lines 51-62), the stent is disclosed to be made of a porous material (col.10, lines 36-38), therefore, pores will be present on both layers.

Referring to claim 20, Brown discloses a degradable plug (matrix 27 extending into pore, or membrane 34, 50; col.8, lines 62-65; col.9, lines 12-21) residing within the plurality of pores.

Referring to claim 26, Brown discloses a stent having structural elements comprising a material selected from the group claimed (col.7, lines 12-19).

Referring to claim 27, Brown discloses a bioactive or active agent selected from the group claimed (col.5, lines 1-27).

Referring to claim 28, Brown discloses a void space (20) comprising a plurality of independent internal cavities along the length of the structural elements (col.5, lines 52-55).

Claims 16 and 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Ragheb et al. (USPN 6,096,070). See figures 4, 6, 7, and respective portions of the specification.

Referring to claim 16, Ragheb discloses an endoluminal stent (10; fig.7) comprising a plurality of structural elements (fig.4, 6, 7) forming a radially expandable cylindrical member, the structural elements having a wall thickness (width of 10 in figures 4, 6, 7), wherein the structural

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elements are comprised of a first region comprising a base layer (14) and a second region comprising a second layer (20) covering the base layer (14), the second region further comprising a layer of void space (area between 14 and 20) intermediate the base (14) and second layers (20) and enclosed therebetween and a plurality of pores (layer 20 is porous, col.10, lines 27-34) passing through the second layer (20) and communicating with the void space and at least one bioactive agent (18) retained within the void space and elutable through the plurality of pores.

Referring to claim 26, Ragheb discloses a stent (10) having structural elements comprising a material selected from the group claimed (col.7, lines 29-47).

Referring to claim 27, Ragheb discloses a bioactive agent (18) selected from the group claimed (col.3, lines 40-56; col.9, lines 20-67).

Referring to claim 28, Ragheb discloses a void space comprising a plurality of independent internal cavities along the length of the structural elements (fig.5, layer 18 is divided into separate cavities by divided 26, col.15, lines 27-32).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller



BRUCE SNOW  
PRIMARY EXAMINER